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EXAMINER	
GUTIERREZ, ANTHONY	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,377	TAYLOR	
	Examiner	Art Unit	
	Anthony Gutierrez	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 22 is objected to because of the following informalities: It is a duplicate of claim 21. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6, 8-11, 13-22, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable by Wittwer et al. (US Patent 6,503,720 B2).

As to claim 1, Wittwer et al. discloses a method to calculate concentration of a substance in a test sample, the method comprising: for at least one observation of a metric for the test sample, finding where on a usable portion of a standard sigmoid curve (Figs. 5 and 6) the observation lies, wherein the usable portion of the standard sigmoid curve is determined via a second derivative of the standard sigmoid curve (Abstract, and col. 12, lines 14 and 15), and the usable portion of the standard sigmoid curve comprises a range of a plurality of points (col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which

includes a number of points to the left and right of the polynomial order in a vertical window parameter); and based on a location of the observation on the standard sigmoid curve, calculating a concentration of the substance (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing the method.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 2, Wittwer et al. discloses the features of claim 1 as addressed above, and further that the sigmoid curve is represented via a four-parameter formula (col. 6, lines 4-10).

As to claim 3, Wittwer et al. discloses the features of claim 1 as addressed above, and further that the standard sigmoid curve represents a sigmoid curve fit to a plurality of observations taken of a reference sample having a known concentration of the substance (col. 9, line 66-col. 11, line 11).

As to claim 4, Wittwer et al. discloses the features of claim 1 as addressed above, and further determining for at least one observation of a metric for the test sample (col. 5, lines 9-25) whether the observation is above a threshold value (step d by finding a

maximum change relative to an initial threshold value), wherein the threshold value is determined via a first derivative of the standard sigmoid curve (step c which determines a threshold as a first derivative of the population as a function of time as addressed in step (b)); and indicating whether the observation is above the threshold value (step d is indicative of a growth rate over time, thus indicating more of the population than at a previous time, thus indicating presence of the substance).

As to claim 5, Wittwer et al. discloses the features of claim 1 as addressed above, and further that the observation indicates optical density for the test sample (col. 12, lines 10-13).

As to claim 6, Wittwer et al. discloses the features of claim 5 as addressed above, and further that the concentration indicates an amount of antibody in the test sample (col. 12, lines 1-4 with respect to inhibition of bacterial growth).

As to claim 8, Wittwer et al. discloses a method comprising: for a plurality of observations of a metric for the test sample, fitting a test sigmoid curve to the observations (Figs. 5 and 6); and calculating a concentration of the substance in the test sample via the test sigmoid curve and a usable portion of a standard curve, wherein the usable portion of the standard sigmoid curve is determined via a second derivative (Abstract, and col. 12, lines 14 and 15) of the standard sigmoid curve (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination), and the usable portion of the standard curve comprises a range of a plurality of points (col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which

includes a number of points to the left and right of the polynomial order in a vertical window parameter).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing a method to calculate concentration of a substance in a test sample.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 9, Wittwer et al. discloses the features of claim 8 as addressed above, and further indicating the concentration of the substance (col. 12, lines 8-13).

As to claim 10, Wittwer et al. discloses the features of claim 8 as addressed above, and further displaying the concentration of the substance (col. 12, lines 8-13).

As to claim 11, Wittwer et al. discloses a method comprising: finding a usable portion of a sigmoid curve(Figs. 5 and 6), wherein the usable portion of the sigmoid curve is determined via a second derivative of the sigmoid curve (Abstract, and col. 12, lines 14 and 15), and the usable portion of the sigmoid curve comprises a range of a plurality of points(col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which includes a number of points to the left and right of the polynomial order in a vertical window parameter).; and calculating a

concentration of the substance in the test sample via the usable portion of the sigmoid curve (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing a method to calculate concentration of a substance in a test sample.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 13, Wittwer et al. discloses a method comprising: determining a usable portion of a sigmoid curve (Figs. 5 and 6) fit to data points representing observations of a reference sample having a known concentration of the substance(Abstract, and col. 12, lines 14 and 15), wherein the usable portion of the sigmoid curve comprises a range of a plurality of points(col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which includes a number of points to the left and right of the polynomial order in a vertical window parameter); and calculating the concentration of the substance in the test sample based on a subset of observations of the test sample, wherein the subset is associated with the usable portion of the sigmoid curve (col. 12, lines 8-13. See also col.

9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

Wittwer et al. does not specifically disclose computer-implemented method of calculating concentration of a substance in a test sample having an unknown concentration of the substance.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 14, Wittwer et al. discloses the features of claim 13 as addressed above. Further it would have been obvious to one of ordinary skill in the art at the time of invention to exclude at least one excluded observation of the test sample responsive to determining the excluded observation is outside the usable portion of the sigmoid curve as it would be common knowledge that this would prevent such outliers from providing inaccurate data.

As to claim 15, Wittwer et al. discloses the features of claim 13 as addressed above, and further that determining a usable portion of the sigmoid curve comprises calculating a second derivative for the sigmoid curve (Abstract, and col. 12, lines 14 and 15).

As to claim 16, Wittwer et al. discloses the features of claim 13 as addressed above, and further that determining a usable portion of the sigmoid curve comprises

designating a portion between a minimum and a maximum of a second derivative for the sigmoid curve as the usable portion of the sigmoid curve (Abstract, and col. 12, lines 14 and 15).

As to claim 17, Wittwer et al. discloses the features of claim 13 as addressed above, and further that a point on the sigmoid curve relating to a threshold for a first derivative of the sigmoid curve is used as a lower threshold to indicate presence of the substance. (col. 5, lines 9-25, step d by finding a minimum change relative to an initial threshold value and step c which determines a threshold as a first derivative of the population as a function of time as addressed in step (b).

As to claims 18, Wittwer et al. discloses a method of determining the concentration of antibody in a blood serum sample, the method comprising: receiving a measurement of concentration of live cells in a test sample, wherein the test sample is generated by adding the serum to cells and a toxin neutralized by the antibody(col. 11, line 65-col. 12, line 31. See also col. 5, lines 9-29); determining whether the concentration of live cells falls within a usable portion of a standard sigmoid curve representing observations taken of a sample having a known concentration of antibody, wherein the usable portion of the standard sigmoid curve comprises a range of a plurality of points (Abstract, and col. 12, lines 14 and 15) and (col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which includes a number of points to the left and right of the polynomial order in a vertical window parameter); and calculating the concentration of the substance in the test sample based on a subset of observations of the test sample, wherein the subset is

associated with the usable portion of the sigmoid curve (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination) ; and responsive to determining the concentration of live cells falls within the usable portion, calculating a concentration via the standard sigmoid curve (Figs. 5 and 6) and (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

Wittwer et al. does not specifically disclose that the method is computer-implemented.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using a computer to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 19, obvious modification of Wittwer et al. implies one or more computer-readable media having computer-executable instructions for performing the method of claim 18 as addressed with respect to claim 18 above.

As to claim 20, Wittwer et al. discloses the features of claim 18 as addressed above, and further that results for plural test samples for plural dilutions of an original test sample are included in the calculating (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

As to claim 21, Wittwer et al. discloses the features of claim 18 as addressed above, and further that concentration of live cells is indicated by optical density of the test sample (col. 12, lines 10-13).

As to claim 22, Wittwer et al. discloses the features of claim 18 as addressed above, and further that concentration of live cells is indicated by optical density of the test sample (col. 12, lines 10-13).

As to claim 24, Wittwer et al. discloses the features of claim 13 as addressed above. Further it would have been obvious to one of ordinary skill in the art at the time of invention to discard the observation responsive to determining the observation is outside the usable portion of the sigmoid curve as it would be common knowledge that this would prevent such outliers from providing inaccurate data.

As to claim 25, Wittwer et al. discloses the features of claim 18 as addressed above, and further that further determining the usable portion of the sigmoid curve via a second derivative of the sigmoid curve. (Abstract, and col. 12, lines 14 and 15)

As to claim 26, Wittwer et al. discloses: a representation of a characteristic sigmoid curve(Figs. 5 and 6); means for designating the usable a usable portion of the characteristic sigmoid curve(Abstract, and col. 12, lines 14 and 15), wherein the usable portion of the characteristic sigmoid curve comprises a range of a plurality of points(col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which includes a number of points to the left and right of the polynomial order in a vertical window parameter); means for receiving at least one observation of a test sample, determining whether the observation of the test sample is

within the usable portion of the characteristic sigmoid curve; and for calculating a concentration for the observation responsive to determining that the observation is within the usable portion of the characteristic sigmoid curve. (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination).

Wittwer et al does not specifically disclose a software system encoded on one or more computer-readable media, the software system comprising

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using a computer to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

As to claim 27, Wittwer et al. discloses the features of claim 26 as addressed above, and further that the usable portion of the characteristic curve is calculated via a second derivative of the sigmoid curve. (Abstract, and col. 12, lines 14 and 15)

As to claim 28, Wittwer et al. discloses the features of claim 26 as addressed above, and further means for determining the usable portion of the sigmoid curve via a second derivative of the sigmoid curve. (Abstract, and col. 12, lines 14 and 15)

As to claim 29, Wittwer et al. discloses the features of claim 26 as addressed above. Further it would have been obvious to one of ordinary skill in the art at the time of invention to reject an observation of the test sample responsive to determining the

observation is outside the usable portion of the sigmoid curve as it would be common knowledge that this would prevent such outliers from providing inaccurate data.

As to claim 30, Wittwer et al. discloses a method to indicate presence of a substance in a test sample, the method (col. 5, lines 9-25) comprising: for at least one observation of a metric for the test sample, determining whether the observation is higher than a threshold value (step d by finding a maximum change relative to an initial threshold value), wherein the threshold value is determined via a first derivative of a standard sigmoid curve (step c which determines a threshold as a derivative of the population as a function of time as addressed in step (b)); and responsive to determining the observation is higher than the threshold value, indicating presence of the substance (step d is indicative of a growth rate over time, thus indicating more of the population than at a previous time, thus indicating presence of the substance).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing the method.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

4. Claims 7, 12, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. (US Patent 6,503,720 B2) in view of Kaastrup (United States Patent Application Publication US 2002/0160012 A1).

As to claim 7, Wittwer et al. discloses the features of claim 6 as addressed above and additionally that the use of second-derivative sigmoid methods for determining a microbial stimulatory response addressed above is with respect to growth concentrations related to test samples A, B, and C (col. 12, lines15-32).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing the method.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

Wittwer does not specifically disclose that the concentration indicates an amount of anti-PA IgG in the test sample.

Kaastrup, however, discloses that IgG is an important antibody in the human immune system that reacts with epitopes (or specific antigens) on invading microorganisms leading to the microorganisms' ultimate destruction (paragraphs 0007-0010). Kaastrup further notes that inclusion of an immunostimulating fragment is used to provide a protective immune response against anthrax (0236).

It therefore would have been obvious to extend the method taught by Wittwer et al. to the indication of amounts of anti-PA IgG in the test samples in order to provide continuous reliable determination of the presence and concentration of potentially lethal anthrax, as detected by sampling an individual's immune response.

As to claim 12, Wittwer et al. discloses a method comprising: for a plurality of dilutions of a test sample, receiving respective measurements of optical density indicating concentration of live cells within the dilutions (col. 12, lines 10-13); via the measurements, calculating a concentration for the test sample via a usable portion of a sigmoid curve representing concentrations of live cells within dilutions of a reference sample having a known quantity (col. 12, lines 8-13. See also col. 9, line 66-col. 11, line 11 for a discussion of the relationship between serial dilutions and concentration determination), wherein the sigmoid curve is represented via a four-parameter logistic technique(col. 6, lines 4-10), and wherein a usable portion of the sigmoid curve is determined via a second derivative of the sigmoid curve (Abstract, and col. 12, lines 14 and 15), , and wherein the usable portion of the sigmoid curve comprises a range of a plurality of points and indicating the concentration of for the test sample. (col. 5, line 60-col. 6, line10, which suggests that for a determination of a second derivative maximum is done in accordance with the Savitzky Golay filter to provide a reliable fractional cycle which includes a number of points to the left and right of the polynomial order in a vertical window parameter).

Wittwer et al. does not specifically disclose one or more computer-readable media comprising computer-executable instructions for performing the method.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using these features to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

Wittwer does not specifically disclose that the concentration indicates an amount of anti-PA IgG in the test sample.

Kaastrup, however, discloses that IgG is an important antibody in the human immune system that reacts with epitopes (or specific antigens) on invading microorganisms leading to the microorganisms' ultimate destruction (paragraphs 0007-0010). Kaastrup further notes that inclusion of an immunostimulating fragment is used to provide a protective immune response against anthrax (0236).

It therefore would have been obvious to extend the method taught by Wittwer et al. to the indication of amounts of anti-PA IgG in the test samples in order to provide continuous reliable determination of the presence and concentration of potentially lethal anthrax, as detected by sampling an individual's immune response.

As to claim 23, Wittwer et al. discloses the features of claim 18 as addressed above and additionally that the use of second-derivative sigmoid methods for determining a microbial stimulatory response addressed above is with respect to growth concentrations related to test samples A, B, and C (col. 12, lins15-32).

Wittwer et al. does not specifically disclose that the method is computer-implemented.

It would have been obvious, however, to one having ordinary skill in the art at the time the invention was made to implement the method using a computer to accomplish the well known technique of computer implementation of algorithm calculation and display since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

Wittwer does not specifically disclose that the concentration indicates an amount of anti-PA IgG in the test sample.

Kaastrup, however, discloses that IgG is an important antibody in the human immune system that reacts with epitopes (or specific antigens) on invading microorganisms leading to the microorganisms' ultimate destruction (paragraphs 0007-0010). Kaastrup further notes that inclusion of an immunostimulating fragment is used to provide a protective immune response against anthrax (0236).

It therefore would have been obvious to extend the method taught by Wittwer et al. to the indication of amounts of anti-PA IgG in the test samples in order to provide continuous reliable determination of the presence and concentration of potentially lethal anthrax, as detected by sampling an individual's immune response.

Response to Arguments

5. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Gutierrez whose telephone number is (571) 272-2215. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571) 272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AG 8/17/07
Anthony Gutierrez

Art Unit 2857

8/17/07

8/20/07
ELISEO RAMOS-FELICIANO
SUPERVISORY PATENT EXAMINER